

Bayer moves to dismiss the Complaint for failure to state a valid claim for relief on

several grounds, but the Court need not go further than their first point, which succeeds. This first point has two elements: 1) the Third Circuit distinguishes inadequate substantiation from false advertising; and 2) the Complaint alleges facts which support the inference of inadequate substantiation, but not false advertising.

As to the first element, Bayer cites the Third Circuit's nonprecedential decision in Franulovic v. Coca Cola Co., 390 Fed. Appx. 125, 128 (3d Cir. 2010), as authority for the proposition that "a New Jersey Consumer Fraud Act claim cannot be premised on a prior substantiation theory of liability." The fact that Franulovic is nonprecedential is not of concern here, because the conclusion is based on a factual assertion which Plaintiffs do not contest: "No New Jersey or Third Circuit decision has applied the prior substantiation theory to the New Jersey Consumer Fraud Act." Id. In response, Plaintiffs argue that they do not rely on a prior substantiation theory, but on the allegation that Bayer's representations are false and misleading. The problem for Plaintiffs, however, is that, as Bayer contends in the second element of its argument, the Complaint fails to allege a sufficient factual basis to support claims that Bayer's representations are false and misleading.

As to this second element, it is clear that Bayer is correct: stripped to its essential factual assertions, the Complaint does not allege sufficient facts to make plausible claims that are all essentially variants of false advertising or misrepresentation.¹ There are several problems here. First, the Complaint alleges merely that the NAD Report criticized Bayer's study as unreliable.

¹ The Complaint asserts four claims which turn on the allegation of misrepresentations: 1) Bayer made misrepresentations to consumers, in violation of the N.J. Consumer Fraud Act; 2) unjust enrichment by retaining the revenues derived from sales based on those misrepresentations; 3) breach of express warranty through the misrepresentations; and 4) breach of implied warranty of merchantability because, essentially, of the misrepresentations.

Plaintiffs have a crucial gap in their logic: how does the unreliability of Bayer's study provide a factual basis for the conclusion that the labeling claims are false? That a research study may be unreliable does not mean that its conclusions are necessarily incorrect.² A dictionary definition of reliability is "the ability to be relied on."³ This captures the meaning of reliability as a descriptor of research studies: did the study produce results which deserve to be relied on?⁴ A reliable study is one which shows signs that, if repeated, it would produce the same results. An unreliable study is one which shows signs that, if repeated, it would not produce the same results. Applying this understanding of reliability to the allegations in the Complaint, the NAD Report stated the opinion that Bayer's study did not show signs that, if repeated, the same results would be obtained. It is a very big leap from this assertion to the conclusion that Bayer's labeling claims are false – too great a leap for the Complaint to pass muster under the pleading requirements of Iqbal. The statement that the study was unreliable does not support any inference about whether, in fact, a single dose of Citrical SR is equivalent to two doses of competing calcium supplements.

With only this foundation, the Complaint offers unsupported, conclusory assertions like the following:

² Moreover, Plaintiffs do not appear to see the problem with contending that a study they characterize as unreliable should be relied upon as proof of the inferiority of Citrical SR.

³ Dictionary.com, <http://dictionary.reference.com/browse/reliability> (last visited February 11, 2013.)

⁴ Plaintiffs appear not to recognize one of the distinctions fundamental to scientific research, the distinction between reliability and validity. See, e.g., http://michaeljmillerphd.com/res500_lecturenotes/Reliability_and_VValidity.pdf (last visited February 11, 2013.)

Bayer's own Pharmacokinetic study demonstrated that Citrical SR did not provide an equivalent (or greater) amount of calcium as compared to the current standard two daily servings or doses of 600 mg tablets . . .

(Compl. ¶ 31.) The Complaint has not pled sufficient facts to support this assertion. The Complaint offers no factual allegations to support a conclusion that a single dose of Citrical SR does not provide equivalent calcium to two daily doses of 600 mg tablets, or that Bayer's study is evidence supporting this conclusion.

A complaint will survive a motion under Rule 12(b)(6) only if it states "sufficient factual allegations, accepted as true, to 'state a claim for relief that is plausible on its face.'" Ashcroft v. Iqbal, 129 S.Ct. 1937, 1949 (2009) (quoting Bell Atlantic v. Twombly, 550 U.S. 544, 570 (2007)). The pleading standard imposed by Federal Rule of Civil Procedure 8(a) will be met if the complaint "pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." Id. (citing Twombly, 550 U.S. at 556.) While the complaint need not demonstrate that a defendant is *probably* liable for the wrongdoing, allegations that give rise to the mere *possibility* of unlawful conduct will not do. Iqbal, 129 S.Ct. at 1949; Twombly, 550 U.S. at 557. The Third Circuit, following Twombly and Iqbal, has held that Rule 8(a) "requires not merely a short and plain statement, but instead mandates a statement 'showing that the pleader is entitled to relief.'" Phillips v. County of Allegheny, 515 F.3d 224, 234 (3d Cir. 2008). This showing must be made by the facts alleged. Id. Under this pleading standard, the Complaint fails to state any valid claim for relief.

The allegations about the NAD Report support the inference that Bayer's study should not be relied on. But that does not mean it is wrong or false. What Plaintiffs have tried to do is to shift the burden of proof onto Bayer. The law, however, requires that Plaintiffs prove, *inter*

alia, that the labeling claims are false. The Complaint, however, fails to point to any facts which make plausible the inference that Plaintiffs have a factual basis for asserting that the labeling claims are false.

The Complaint asserts vaguely that “studies have demonstrated that the calcium carbonate, which is the largest source of calcium in Citrical SR has much lower rates of bioavailability than calcium citrate.” (Compl. ¶ 46.) This almost sounds like a relevant factual allegation, except that it doesn’t say anything relevant. How are such studies probative of the falseness of Bayer’s labeling claims? Given that the Complaint alleges that “[c]alcium carbonate supplements are more commonly available” than calcium citrate supplements, a comparison of calcium carbonate to calcium citrate products does not appear to be relevant to what is at issue here, which is the comparison of one calcium carbonate product, Citrical SR, to other calcium carbonate products in the marketplace. (Compl. ¶ 23.)

Plaintiffs summarize their position in opposition to the motion to dismiss as follows: “Plaintiffs allege these statements are false and misleading. Specifically, they allege that Citracal SR is a fundamentally defective product that actually provides inferior absorption of calcium, and it cannot possibly provide the recommended amount of calcium in a single daily dose.” (Pls.’ Opp. Br. 1.) As discussed, the Complaint fails to plead sufficient facts to make plausible any claim that Citrical SR is an inferior and defective product which Bayer has falsely advertised or misrepresented. Inasmuch as all the claims in the Complaint are predicated on this allegation of misrepresentation, all the claims must be dismissed.

The motion to dismiss will be granted, and the Complaint will be dismissed without prejudice. Plaintiffs will be granted leave to file an amended Complaint within 30 days of the

date of entry of this Order.

For these reasons,

IT IS on this 11th day of February, 2013

ORDERED that Bayer's motion to dismiss the Complaint for failure to state a valid claim for relief (Docket Entry No. 15) is **GRANTED**, and the Complaint is hereby **DISMISSED** without prejudice; and it is further

ORDERED that Plaintiffs are granted leave to file an Amended Complaint within 30 days of the date of entry of this Order.

s/Stanley R. Chesler
STANLEY R. CHESLER, U.S.D.J.